Chapter 1
REGULATORY ORGANIZATION

This chapter (revised June 10, 2005) contains the following sections:

1-1 INTRODUCTION

The purpose of this chapter is to provide an overview of the organizational structure of the offices involved in compliance related functions within FDA. It is not the intent to provide a complete description of FDA's organizational structure. FDA's functional statement for each office may be found in various chapters of FDA's Staff Manual Guide (SMG). This guide is available on FDA's Intranet Website.

This Regulatory Procedures Manual (RPM) chapter is divided into sections based on major organizational units, and includes a section for all Centers and the Office of Regulatory Affairs (ORA).

1-2 OFFICE OF REGULATORY AFFAIRS (ORA)

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS (ACRA)

ORA is under the direction of the Associate Commissioner for Regulatory Affairs. The functional statements for ORA are:

- Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals.
- Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner.
- Stimulates an awareness within the Agency of the need for prompt and positive action to ensure compliance by regulated industries; works to assure an effective and uniform balance between voluntary and regulatory compliance and Agency responsiveness to consumer needs.
- Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.

- Executes direct line authority over all Agency field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the Agency through which Headquarters offices obtain field support services.
- Provides direction and counsel to Regional Food and Drug Directors (RFDDs) in the implementation of policies and operational guidelines that form the framework for management of Agency field activities.
- Develops and/or recommends to the Commissioner policy, programs, and plans for activities between the Agency and state and local agencies; administers the Agency's overall Federal-State program and policy; coordinates the program aspects of Agency contracts with state and local counterpart agencies.
- Evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.
- Directs and coordinates the Agency's emergency preparedness and civil defense programs.
- Operates the Federal Medical Products Quality Assurance Program for the Agency.

OFFICE OF ENFORCEMENT (HFC-200)

The functional statements for the Office of Enforcement are:

- Advises and assists the Associate Commissioner and other key officials on regulations and compliance matters that impact on policy development, implementation, and long-range program goals.
- Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy and recommends policy to the Associate Commissioner.
- Stimulates an awareness within the Agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between regulatory compliance and Agency responsiveness to consumer needs.
- Acts as liaison with other federal agencies on Agency compliance matters and encourages an effective and appropriate balance between voluntary and regulatory compliance.
- Evaluates and coordinates proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.
- Directs and coordinates with the Office of Regional Operations (ORO), other Agency components, and Office of Chief Counsel (OCC), new or novel cases which may be precedent-setting.
- Resolves appeals when proposed compliance actions are disapproved by the Centers or OCC.
- Serves as the Agency focal point for activities relating to the Federal Medical Products Quality Assurance Program and maintains liaison with other government agencies procuring medical supplies; issues final administrative approval for quality assurance of specific products/firms.

There are three divisions within the Office of Enforcement:

Division of Compliance Management and Operations
Division of Compliance Policy
Division of Compliance Information and Quality Assurance

DIVISION OF COMPLIANCE MANAGEMENT AND OPERATIONS (HFC-210)

The functional statements for the Division of Compliance Management and Operations are:

- Performs final administrative review of proposed legal actions for sufficiency of evidence and coordinates the acquisition of additional evidence needed through the appropriate Centers and the field offices.
- Resolves disputes or other problems encountered during case review to ensure that Agency decisions are consistent.
- Provides guidance for and participates in the development of new, novel, or precedent-setting cases. Provides counsel to the field on compliance matters. Interprets policy and major action decisions and provides guidance on their application.
- Evaluates terminated legal cases to determine effectiveness in bringing about correction and to evaluate enforcement strategies and evidentiary and other problems. Performs trend analysis and identifies actual and potential problem areas. Advises Agency regarding actions initiated through case news digest.
- Participates in the design and implementation of training programs for Headquarters and field compliance personnel.
- Serves as the Agency clearance point and coordinator for all warrants, both administrative and search and seizure.
- Serves as the Agency focal point for guidance on recall plans and procedures. Directs and coordinates field activities in support of all product recalls. Maintains liaison with other Agency components, industry, and other government agencies to ensure proper implementation and completion of recall plans and activities.
- Evaluates all Team Biologics cases and is responsible for initial recommendations of advisory actions.

DIVISION OF COMPLIANCE POLICY (HFC-230)

The functional statements for the Division of Compliance Policy are:

- Develops, coordinates, and monitors the development of new or modified Agency compliance policies and regulatory procedures for all domestic and imported products regulated by the Agency. Directs and coordinates the preparation and maintenance of compliance publications including the Compliance Policy Guides Manual, the Regulatory Procedures Manual, and the Enforcement Story.
- Reviews and participates in the development of regulations for all program areas.
- Reviews all new legislative proposals for the Office of Enforcement
- Reviews all Agency planned initiatives associated with the regulatory planning process to determine the need for an enforcement strategy. Reviews initiatives and makes recommendations to the Director, Office of Enforcement, concerning the adequacy of enforcement strategies.

- Serves as the Agency focal point for information on compliance policies and regulatory procedures with other government agencies including foreign, other federal agencies and state agencies.
- Coordinates requests from other federal agencies such as the FTC, SEC and USDA regarding information disclosure issues.
- Develops policy and responds to requests for testimony of Agency employees from foreign governments, other federal agencies, state and local government agencies, as well as private attorneys.
- Provides policy and program direction to Agency units carrying out the objectives of the Nonclinical Laboratory Compliance Program. Monitors compliance activities to assure uniform application of compliance policy and monitors Agency performance in meeting program accomplishment projections for the Nonclinical Laboratory Compliance Program.
- Serves as a lead agency resource communicating with internal and external Nonclinical Laboratory Compliance Program constituents to provide expert technical guidance, advice, information, interpretation, analysis and training relative to the agency's Good Laboratory Practice regulations.
- Leads international regulatory harmonization activities and international and interagency inspection activities under Nonclinical Laboratory Compliance Program Memoranda of Understanding.
- Serves as agency liaison to other Federal Agencies, e.g.; USDA, EPA, NIH, NTP, for coordination of Nonclinical Laboratory Compliance Program issues.
- Serves as Agency Research Integrity Liaison Officer (ARILO) and Agency Intramural Research Integrity Officer (AIRIO). Coordinates and oversees the agency's overall activities and policies related to research integrity in both intramural and extramural research supported by FDA.
- Serves as the agency focal point to address coordination of policy and program issues regarding enforcement actions for Nonclinical Laboratory, IRB, and Clinical Investigator programs.
- Serves as the Agency focal point for resolving intra-agency enforcement policy issues at the Headquarters level and for Headquarters/field operational and compliance relations on Agency compliance policy.
- Serves as the focal point for coordinating the Freedom of Information (FOI) activities within ORA. Prepares responses to FOI requests. Develops guidelines for the field and coordinates field implementation of provisions for the Privacy Act and FOI Act.

DIVISION OF COMPLIANCE INFORMATION AND QUALITY ASSURANCE (HFC-240)

The functional statements for the Division of Compliance Information and Quality Assurance are:

- Develops and maintains liaison with other government agencies procuring medical products; develops and maintains operational agreements and systems; serves as the FDA focal point for all activities relating to the government-wide quality assurance program.
- Receives and processes requests from other federal agencies for quality assurance support; serves as the final administrative approval authority for quality assurance evaluations of specific products and firms; provides quality assurance evaluation

responses to requesting agencies.
- Maintains liaison, coordinates, and directs field and Headquarters activities relating to the government-wide quality assurance program.
- Monitors the Agency's Field Accomplishments and Compliance Tracking System (FACTS).
- Manages the Agency's program for providing quality assurance information to state and foreign governments in support of their procurements or determinations of admissibility of U.S. products.
- Publishes the FDA Gold Disk and Eureka Disk.
- Coordinates policy development on electronic records and electronic recordkeeping.
- Manages the Agency's Turbo Establishment Inspection Report (EIR) system.

ORA FIELD ORGANIZATION

The ORA field organization is divided into regional offices. The regional offices are under the direction of Regional Food and Drug Directors (RFDDs) who report to the ACRA. There are five regional offices. They are located as follows:

1.	Northeast Region	Jamaica, NY
2.	Central Region	Philadelphia, PA
3.	Southeast Region	Atlanta, GA
4.	Southwest Region	Dallas, TX
5.	Pacific Region	Oakland, CA

There are two to seven district offices within each region for a total of 19 districts. Each district office is usually comprised of three to four branches, including either a Compliance Branch or an Enforcement Branch, which is the primary regulatory contact within a district office.

1-3 CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY (HFM-600)

The functional statements for the Office of Compliance and Biologics Quality are:
- Monitors the quality of marketed biological products through surveillance, inspections, and compliance programs, and coordinates testing of marketed products with other components of the FDA.
- Identifies and recommends appropriate action, in coordination with other CBER/Agency components, on the results of continuing surveillance and evaluation of advertising and clinical experience reports submitted by manufacturers and sponsors of products regulated by the Center.
- Develops policies and procedures, receives, reviews, evaluates, and takes appropriate action on establishment license applications submitted by manufacturers (except blood and plasma establishments) in coordination with other CBER components, and establishes written and reference standards for biological products establishments (except blood and plasma establishments).
- Advises the Center Director and other Agency officials on emerging and significant compliance issues for biological products and serves as CBER's focal point for

surveillance and enforcement policy.
- Coordinates CBER's participation in the inspection of biological product manufacturing facilities.
- Develops, with other CBER/Agency components, compliance standards for biological products, including Current Good Manufacturing Practice (CGMP) regulations, ensures their uniform interpretation and evaluates industry's conformance with CGMP in manufacturing biological products.
- Directs CBER's bioresearch monitoring program, enforcement, and recall programs for biological products.
- Except for programs relating to consumer affairs activities, develops biological product compliance and surveillance programs, coordinates and directs their field implementation, and advises other CBER components on these programs.
- Provides guidance to Headquarters and field personnel in the development of evidence to support enforcement actions.
- Coordinates all CBER-field compliance activities, including planning and field assignments.
- Coordinates CBER's import and export programs.
- In coordination with other CBER components, responsible for lot release of biological products including testing products and review of protocols submitted for release by manufacturers. Also maintains a reference reagent program.
- Reviews, and evaluates all administrative action recommendations including suspension, revocation, denial of license, debarment, disqualification of clinical investigators, and recommended civil and criminal actions, including seizure, injunction, and prosecution based on findings of inspections and investigations.
- Coordinates CBER's application integrity policy.
- In coordination with other Agency components, formulates policy in the areas of compliance and biologics quality including enforcement, good manufacturing practices, and labeling including advertising and promotion, and drafts guidance documents for other Agency components and regulated industry on these subjects including documents regarding error and accident reporting, content and format of chemistry, manufacturing and controls information and establishment information, and container closure systems for packaging of human drugs and biologics.
- Reviews and enforces regulations pertaining to product labeling including proprietary names, labels, package inserts, and promotion and advertising material. Formulates and establishes policy for the regulation of promotional activities including advertisements, promotional labeling, and promotional practices.
- Plans and develops, in coordination with other Agency and CBER components, information and education activities related to labeling and advertising approval for health professionals, consumers, and Agency staff.

There are three divisions within the Office of Compliance and Biologics Quality:

Division of Case Management
Division of Inspections and Surveillance
Division of Manufacturing and Product Quality

DIVISION OF CASE MANAGEMENT (HFM-610)

The functional statements for the Division of Case Management are:

- Reviews and evaluates administrative action recommendations including suspension, revocation, denial of license and debarment. Reviews recommended civil and criminal actions, including seizure, injunction, and prosecution. Prepares documents required for such enforcement actions and manages cases after actions are taken.
- Coordinates support for ongoing litigation and contested cases with the Office of Chief Counsel and the Department of Justice, including the identification and preparation of expert witnesses.
- In coordination with the Office of Communications, Training, and Manufacturers Assistance, provides training for CBER and other Agency personnel regarding evidence development in support of administrative and legal actions.
- Provides primary support within the Office of Compliance and Biologics Quality for Agency Ad Hoc Committee Meetings relating to proposed enforcement action against products, manufacturers or other individuals associated with CBER regulated products.
- Develops enforcement standards for direct reference authority to FDA district offices for issuance of Warning Letters and reviews and evaluates Team Biologics and district generated recommendations for the issuance of Warning Letters for which direct reference authority had not been granted.
- Coordinates CBER's application integrity policy.
- Directs and coordinates CBER's review of applications for export of unapproved biological products.
- Provides assessment of the compliance status of regulated firms within CBER's purview (compliance status checks).
- Reviews, evaluates, and monitors material associated with promotion, advertising, conferences, exhibits, and similar types of media for all biological products, new drugs, and medical devices approved by CBER. Participates in actions to remedy violative promotion.
- Serves as the focal point within CBER for voluntary and FDA requested recalls including tissue recall orders.

DIVISION OF INSPECTIONS AND SURVEILLANCE (HFM-650)

The functional statements for the Division of Inspections and Surveillance are:

- Coordinates and provides support and guidance to district offices for investigations and surveillance inspections.
- Works with the Office of Regulatory Affairs (ORA) to prepare inspection work plans and allocate resources for the biological product inspection program.
- Develops guidance and other training programs in conjunction with CBER components, to promote industry compliance and for use in training Headquarters and field inspection staffs.
- Develops and updates compliance programs on behalf of CBER.
- Manages the biological compliance surveillance activities including review of transfusion-related fatality reports.
- Plans and directs investigation and surveillance assignments in response to reports regarding product defects, adverse events, error and accident reports, and allegations of violative activity. Evaluates the related inspection and investigation reports.

- Manages the Bioresearch Monitoring programs for CBER, including clinical investigator disqualifications. Reviews, evaluates, and classifies Establishment Inspection Reports and prepares Warning Letters.
- Coordinates Office follow-up and response to complaints related to investigational products and clinical trials.
- Working with the Office of Communications, Training, and Manufacturers Assistance, provides guidance to industry and government concerning bioresearch monitoring policies and regulations.
- Manages CBER's product shortage program.
- Promotes uniformity between CBER and ORA with regard to conducting inspections and the implementation of Current Good Manufacturing Practices (CGMPs) policy.
- Serves as CBER's contact for Team Biologics issues during inspections.
- Supports the CBER pre-approval inspection program.
- Serves as the CBER contact for other federal agencies concerning enforcement matters, and coordinates review of these matters with other Agency components as appropriate.

DIVISION OF MANUFACTURING AND PRODUCT QUALITY (HFM-670)

The functional statements for the Division of Manufacturing and Product Quality are:

- Reviews, evaluates, and takes action on Investigational New Drugs applications (INDs), license applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER). Performs Chemistry, Manufacturing and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews.
- Reviews manufacturers' submissions with respect to such tests.
- Develops and administers the biological products lot release program. Reviews manufacturers' submissions for licensed biological product lots. Receives, maintains, and distributes samples of biological products submitted for testing.
- In coordination with the Office of Communications, Training, and Manufacturers Assistance, provides expert technical and regulatory guidance and training to CBER and other agency components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality.
- Leads prelicense and preapproval inspections, and participates in routine GCMP inspections of establishments manufacturing biological products. Participates in the preparation of inspection reports as part of an inspection team and evaluates the firm's corrective actions.
- Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

1-4 CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

OFFICE OF COMPLIANCE (HFD-300)

The Office of Compliance assures that safe and effective drugs are available to the American people. The substructure of the Office has been modified by changing the titles of the Division of Labeling and Nonprescription Drug Compliance to the Division of New Drugs and Labeling

Compliance and the Division of Prescription Drug Compliance and Surveillance to the Division of Compliance Risk Management and Surveillance.
In addition, the Office established the Surveillance and Data Analysis Branch within the Division of Compliance Risk Management and Surveillance, and the Over-the-Counter (OTC) Drugs and Health Fraud Branch and the Prescription Drug Branch within the Division of New Drug Labeling and Compliance. The reorganization improved the Office's ability to assess and prioritize risks by enhancing surveillance and analysis capabilities. The functional statements for the Office of Compliance are:

- Protects the American public from unsafe and ineffective drugs by addressing public health risks associated with legal violations.
- Develops and oversees drug compliance programs designed to reduce consumer exposure to risks of unsafe and ineffective drugs.
- Monitors the quality of human drugs through inspectional coverage, product testing, and other pre- and post-market surveillance activities.
- Advises the Center Director and other Agency officials on regulatory and enforcement issues involving human drugs.
- Coordinates Center-Field relations and provides support and guidance to field offices on case development and regulatory actions; ensures uniform interpretation of standards.
- Develops policies and compliance strategies to ensure that OTC and Rx drugs are of high quality, properly labeled, safe, pure, and meet applicable drug approval requirements.
- Develops policy and standards to achieve high product quality through application of current good manufacturing practice requirements. Coordinates surveillance and pre-approval inspections.
- Coordinates evaluation and classification of drug recalls and provides Center coordination with field offices for implementation of recalls; monitors resolution of drug shortage situations involving compliance issues.
- Implements programs and projects to identify, assess, and prioritize the public health significance of legal violations and develops and utilizes innovative enforcement strategies to reduce public health risks associated with legal violations.

There are three divisions within the Office of Compliance:

Division of New Drugs and Labeling Compliance
Division of Manufacturing and Product Quality
Division of Compliance Risk Management and Surveillance

DIVISION OF NEW DRUGS AND LABELING COMPLIANCE (HFD-310)

The Division's primary responsibility is to protect the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act as it relates to over-the-counter drugs, prescription (Rx) drugs, and drugs falling within the health fraud program area.

The Division consists of five teams, the OTC Drugs Team, the Internet and Health Fraud Team, the Compounding Team, the New Drugs and Labeling Team, and the Import-Export Team. The functional statements for the Division of New Drugs and Labeling Compliance are:

- Protects the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act as it relates to over-the-counter (OTC) drugs, prescription (Rx) drugs, and drugs falling within the health fraud program area.
- Develops compliance strategies, programs and policy guides to ensure that all OTC and Rx drugs marketed in the United States are properly labeled and meet applicable new drug requirements and to remove from the market fraudulent drug products that pose direct or indirect public health risks.
- Maintains the integrity of imported drug products by assuring their compliance with applicable legal requirements.
- Provides guidance and consults on export policies and procedures.
- Directs field inspections and investigations and recommends, directs and/or coordinates case development and compliance actions regarding OTC, Rx, and health fraud drug products.
- Provides enforcement and litigation support and guidance for OTC, Rx, and health fraud drugs, including support for State Attorney General and Office of Criminal Investigation cases.
- Provides guidance and interpretation of drug establishment registration and drug product listing regulations involving domestic and imported drug products.
- Develops legislative proposals, implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities relating to pharmacy compounding.
- Monitors the Internet in support of Division enforcement initiatives, actions and outreach programs.
- Prioritizes unapproved drugs identified for regulatory action using risk based assessment and develops compliance strategies to address the most significant legal violations.

DIVISION OF MANUFACTURING AND PRODUCT QUALITY (HFD-320)

- The Division is the Agency focal point for comprehensive regulatory oversight of the human drug manufacturing industry to ensure that drug products offered in the U.S. marketplace comply with the adulteration provisions of the Federal Food, Drug, and Cosmetic Act.
- The Division consists of the Case Management Branch and the Investigations and Preapproval Compliance Branch. At the Division level, the Recall and Drug Shortage Program and coordination of Office emergency operations are performed under the Deputy Director. The functional statements for the Division of Manufacturing and Product Quality are:
- Serves as Agency focal point regarding compliance of establishments and products with current good manufacturing practices (CGMP) and other adulteration provisions of the Federal Food, Drug and Cosmetic Act.
- Assures the quality and purity of marketed human drug products through enforcement of the CGMP regulations for the manufacture, testing and holding of human drugs. Develops and directs the CDER drug product quality enforcement programs.
- Provides clear and consistent guidance to FDA field personnel, industry and foreign governments on manufacturing quality requirements for human drug products.
- Assures rapid access to quality new human drugs by verifying new drug application commitments, CGMP compliance, and supporting data before and after application

approval; develops and implements strategies for alleviation of drug shortages/drug supply problems.
- Ensures that the appropriate corrective action is taken when human drug products are unsafe or adulterated; manages the CDER product recall program and coordinates Office of Compliance emergency operations.
- Develops guidance materials and educational programs to promote compliance with drug good manufacturing practice requirements.
- Develops Agency compliance policy for enforcement of the Federal Food, Drug, and Cosmetic Act regarding drug product quality.
- Processes regulatory actions involving drug product quality requirements and supports litigation arising from regulatory actions.
- Promotes goodwill and cooperation between the United States and foreign governments through the Export Certificate Program, which enables American manufacturers to export their products to foreign customers and governments and demonstrates that drugs for export meet applicable legal standards.
- Proposes and implements agreements with foreign governments for harmonization of requirements and program efficiencies for assuring human drug product quality.

DIVISION OF COMPLIANCE RISK MANAGEMENT AND SURVEILLANCE (HFD-330)

The Division's primary responsibility is to advance the Office mission through implementation of programs and projects to identify, assess and prioritize legal violations based upon their public health significance. This approach requires qualitative and quantitative data analyses and the use of strategic problem solving to target compliance actions and develop innovative enforcement strategies for reducing public health risks associated with violative drug products.

The Division is composed of a Risk Management and Strategic Problem Solving Team and a Surveillance and Data Analysis Branch. The Surveillance and Data Analysis Branch consists of the Surveillance Programs Team and Data Analysis and Information Team. The functional statements for the Division of Compliance Risk Management and Surveillance are:

- Fosters the use of risk-based approaches to compliance and enforcement actions undertaken by the Office.
- Applies qualitative and quantitative analysis to identify, assess and prioritize legal violations for compliance action based upon their public health significance. Utilizes strategic problem solving to select projects for intervention and to develop and evaluate the effectiveness of such interventions in reducing the public health risks associated with violative drug products.
- Works closely with other agency units in areas of strategic planning, GPRA implementation, identification of priorities, and development of risk-based compliance initiatives.
- Monitors the quality of the nation's drug supply through post-market surveillance activities, including overseeing the sampling and analysis of drugs and directing compliance activities pertaining to the post-market Adverse Drug Experience reporting requirements.
- Develops expertise in working with Office and agency databases, including drug surveys, Drug Quality Reporting and NDA Field Alert System, AERS, Drug Recalls and Shortages, Establishment Evaluation System, Drug Registration and Listing System,

Prescription Drug Marketing Act (PDMA), DESI Federal Register database, Turbo EIR and FACTS. Also establishes familiarity with relevant databases outside the office and agency.

1-5 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

OFFICE OF COMPLIANCE (HFZ-300)

The Office of Compliance (OC) develops, directs, coordinates, evaluates, and monitors compliance programs covering regulated industry. OC conducts field tests and inspections when necessary for regulatory purposes, evaluates industry quality control and testing programs to assure compliance with regulations, and provides advice to Agency field offices on, and manages Center activities relating to, legal actions, case development, and contested case assistance, and coordinates all field planning activities and issues all field assignments for the Center.

There are four divisions in the Office of Compliance:

Division of Risk Management Operations
Division of Bioresearch Monitoring
Division of Enforcement A
Division of Enforcement B

DIVISION OF RISK MANAGEMENT OPERATIONS (HFZ-305)

The functional statements for the Division of Risk Management Operations are:

- Advises and supports Office officials and staff regarding all policies and procedures relating to administrative support activities.
- Provides analysis activities for Office, Center and Agency senior management in the development and implementation of risk-base regulatory and enforcement activities
- Advises Office officials and staff regarding management information system initiatives and serves as the Office liaison to other Center and Agency components on all such matters. Plans, coordinates, and implements an Office Information Technology strategic plan.
- Provides information for requests from external as well as internal sources. Coordinates and processes Freedom of Information Requests (FOI) and issues certificates for requests to export approved medical devices and non-approved medical devices under 801(e) of the Federal Food, Drug, and Cosmetic Act (the Act).
- Coordinates the Center's administrative activities with field offices as well as internal regulatory actions.
- Develops, coordinates, and/or conducts medical device and electronic products training programs for field personnel and state and local agencies in coordination with other Center and Agency components.
- Develops, processes information for, and maintains the medical device registration and product listing system; develops and monitors contracts for data processing; ensures industry compliance with reporting requirements through a certification program; and develops and maintains a document tracking system.

There are two branches within this Division:

Field Operations Branch
Information Processing and Office Automation Branch

DIVISION OF BIORESEARCH MONITORING (HFZ-310)

The functional statements for the Division of Bioresearch Monitoring are:

- Enforces the Medical Device Amendments of 1976 and 1992 and the Safe Medical Devices Act of 1990 as they relate to investigational devices.
- Manages and coordinates the administrative and regulatory responsibilities of the Agency's Bioresearch Monitoring Program for medical devices. Prepares related Warning Letters and other correspondence. Ensures corrective actions taken by firms inspected under the Bioresearch Monitoring Compliance Program are acceptable.
- Assigns, directs, and coordinates on-site inspections of sponsors and investigators of preclinical and clinical device product studies, institutional review boards, commercial clinical testing facilities, and nonclinical toxicology laboratories in collaboration with the Agency's field organization.
- Provides regulatory guidance and interpretations of the informed consent, institutional review board, and the investigational device exemption regulations to the field and industry.
- Designs, implements, and evaluates surveillance and compliance programs in the areas of preclinical and clinical investigational device product investigations. Manages the premarket approval data audit program to ensure the integrity of data submitted to the Agency.
- Coordinates and implements the Agency's Application Integrity Policy for medical devices.

There are two branches within the Division of Bioresearch Monitoring (HFZ-310):

Program Enforcement Branch
Special Investigations Branch

DIVISION OF ENFORCEMENT A (HFZ-320)

Enforces medical device regulations as they relate to general surgical devices, dental; ear, nose, and throat (ENT); and ophthalmic devices; urology, gastroenterology; and obstetrics/gynecology (OB/GYN) devices; and general hospital devices.

There are four branches within this division:

Dental, ENT, and Ophthalmic Devices Branch
General Hospital Devices Branch
General Surgical Devices Branch
OB/GYN, Gastroenterology, Urology Devices Branch

DIVISION OF ENFORCEMENT B (HFZ-340)

Enforces medical device regulations as they relate to cardiovascular, therapeutic radiologic, orthopedic, physical medicine, anesthesiology, and neurological devices.

There are two branches within this division:

Cardiovascular and Neurological Devices Branch
Orthopedic, Physical Medicine and Anesthesiology Devices Branch

The functional statements for the Divisions of Enforcement A and B, as they relate to each division's specialty areas, are:

- Manages and coordinates activities associated with administrative and regulatory actions.
- Develops, interprets, and issues policy guidance in response to specific requests from the medical device, trade associations, other federal agencies, other countries, state agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practice (GMP) and standards for electronic products.
- Plans, initiates, coordinates, and conducts medical device and electronic product inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.
- Identifies the need for and directs the development of compliance policy guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

OFFICE OF COMMUNICATION, EDUCATION AND RADIATION PROGRAMS (HFZ-200)

DIVISION OF MAMMOGRAPHY QUALITY AND RADIATION PROGRAMS (HFZ-240)

Enforces the Mammography Quality Standards Act and the electronic product radiation control provisions of the Federal Food, Drug, and Cosmetic Act as they relate to medical diagnostic and therapeutic and non-medical radiation-emitting electronic products.

There are six branches within this division,

Information Management Branch
Accreditation and Certification Branch
Radiation Programs Branch
Inspection and Compliance Branch
Electronic Product Devices Branch
Diagnostic X-ray Devices Branch

The latter three have compliance functions.

The functional statements for the Division of Mammography Quality and Radiation Programs are:

- Manages and coordinates activities associated with administrative and regulatory actions regarding radiation-emitting electronic products and mammography facilities.
- Develops, interprets, and issues policy guidance in response to specific requests from the medical device and electronic product industries, mammography facilities, professional and trade associations, other federal agencies, other countries, state agencies, and the general public.
- Develops, reviews, and revises new and amended regulations including good manufacturing practice (GMP) and performance standards for radiation-emitting electronic products and quality standards for mammography facilities.
- Plans, initiates, coordinates, and conducts inspections and investigations of manufacturers and certain specific users of radiation-emitting medical diagnostic, non-medical, and medical therapeutic devices. Also includes inspections and investigations of mammography facilities.
- Reviews and evaluates design, test, and production data and reports from manufacturers of radiation-emitting medical and non-medical diagnostic and therapeutic devices to ensure compliance with promulgated standards and regulations.
- Identifies the need for and directs the development of compliance policy guidance and programs to facilitate compliance by manufacturers of radiation-emitting medical and non-medical diagnostic and therapeutic devices, as well as mammography facilities.
- Develops, coordinates, reviews, and revises medical device industry GMP regulations as they pertain to radiation-emitting diagnostic and therapeutic devices.
- Develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (HFZ-440)

The Office of In Vitro Diagnostic Device Evaluation and Safety enforces medical device regulations as they relate to in vitro diagnostic devices. The functional statements for this office relating to compliance and enforcement activities involving in vitro diagnostic devices are:

- Manages and coordinates activities associated with administrative and regulatory actions.
- Develops, interprets, and issues policy guidance in response to specific requests from the in vitro diagnostic device industry, trade associations, other federal agencies, other countries, state agencies, and the general public. Develops, reviews, and revises new and amended regulations and standards for in vitro diagnostic devices.
- Plans, initiates, coordinates, and conducts inspections and investigations of in vitro diagnostic device manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with regulations.
- Identifies the need for and directs the development of compliance policy guides and programs to facilitate compliance by manufacturers. Develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

1-6 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

OFFICE OF COMPLIANCE (HFS-600)

The functional statements for the Office of Director are:

- Serves as the primary contact between the Center and the FDA Field organization.
- Reviews regulatory actions for adequacy of evidence and consistency across programs; and when appropriate, refers cases to the appropriate program offices for science and technical review.
- Reviews proposed recalls for adequacy of evidence and consistency.
- In collaboration with other Center Offices, assures that all field compliance and enforcement policy is consistent.
- Coordinates development and implementation of field programs and assignments with other Center offices and the Office of Regional Operations. Evaluates field accomplishments and provides feedback to Center and field management.
- Plans, develops, publishes and promotes guidance to implement sound public health practices, food safety/security, compliance/enforcement, and regulatory programs. Provides information, training, and technical assistance to implement CFSAN's guidance and regulations and supports ORA in the development of inspectional guides for field personnel.
- Administers the federal portion of the Federal/State cooperative programs and sets policy as it relates to cooperative programs administered by the National Conference on Interstate Milk shipments (NCIMS), the Conference for Food Protection (CFP) and the International Shellfish Sanitation Conference (ISSC). Serves the FDA representative to these conferences.
- Supports the implementation of preventive control initiatives and programs in the preparation, packaging, and holding of foods in cooperation with other CFSAN offices.
- Serves as the Chair for the Center's Compliance Council.
- Serves as experts, where appropriate, in issues in which the Office's personnel have specific technical expertise to support other CFSAN Offices in policy development and compliance case reviews.
- Recommends to the Center's Compliance Council of CFSAN Offices the development of new policy or technical guidance where widespread or emerging compliance problems are noted.
- Maintains liaison with the Field Food Committee.
- Plans and develops approaches to implement regulatory responsibilities in the Interstate Travel Program.

The functional statements for the Emergency Coordination and Response Staff are:

- Leads the Center in coordinating, directing, and assisting ORA (field and headquarters) with foodborne outbreak investigations and coordination and other emergency activities involving food products, dietary supplements and cosmetics.
- Develops, reviews, recommends and maintains policies, procedures, protocols and guidance for investigating outbreaks and responding to emergencies involving foods, dietary supplements and cosmetics.
- Provides technical expertise in outbreak and trace back investigation.

- Serves as the Center point of contact to the Centers for Disease Control and Prevention (CDC), international, federal, state and local Public Health and Agricultural agencies during outbreak and other emergency activities involving food products, dietary supplements and cosmetics.
- Serves as the Center liaison to the Council of State and Territorial Epidemiologists, international, federal, state and local Public Health and Agricultural agencies in coordinating and planning activities and programs related to outbreak and emergency response programs.

There are three divisions within the Office of Compliance:

Division of Enforcement
Division of Field Programs
Division of Cooperative Programs

DIVISION OF ENFORCEMENT (HFS-605)

The functional statements for the Division of Enforcement are:

- Facilitates the submissions and management of regulatory actions. Serves as the Center point of contact for enforcement policy and priority inquiries from ORA (field and headquarter) units.
- Evaluates inspectional, investigational and analytical evidence and determines whether to pursue a regulatory action or alternative remedy.
- Recommends to the Center's Compliance Council or CFSAN Offices the development of new policy or technical guidance where widespread or emerging compliance problems are noted.
- Develops innovative enforcement solutions to novel, complex and precedent setting regulatory problems. Guides field office activities, when necessary, in developing scientifically and legally supportable actions.
- Assists OCC, the Department of Justice, FDA field compliance officers and U.S. Attorneys in drafting declarations and other legal documents, obtaining experts, responding to interrogatories, and providing trial or other requested assistance. Represents the Center at enforcement negotiations.
- Evaluates recall recommendations, obtains scientific and technical support and assures that recall actions are consistent with Agency and Center Policies.
- Develops direct reference authority to be given to ORA field offices in cooperation with other Center Offices. Develops and maintains procedures for direct reference authority. Assures that direct reference authority actins are consistently applied across ORA field offices.
- Evaluates foreign establishment inspection reports, import samples analyses, field exam results and other information and determines whether to pursue regulatory action.
- Gathers, develops and evaluates information to address systemic and/or countrywide problems and recommends compliance solutions that are prioritized, consistent and logical.
- Plans and develops approaches to implement regulatory responsibilities in the Interstate Travel Program.
- Maintains the Center-wide tracking and precedent file systems. Assures these systems meet current needs and reflect the best use of available technologies, when feasible.

- Serves as an expert resource on foreign product compliance through knowledge and evaluation of country infrastructure, Establishment Inspection Report (EIR) review and sample results. Participates in agency discussions, decisions and fact finding for related import and international issues for a foreign country, product and industry assessment.

There are one staff and two branches within the Division of Enforcement:

Special Investigations, Case Development Recalls Staff
Import Branch
Domestic Branch

DIVISION OF FIELD PROGRAMS (HFS-615)

The functional statements for the Division of Field Programs are:

- Develops and issues compliance programs and assignments in coordination with the CFSAN Offices. Recommends field resource utilization to accomplish center priorities for implementation by the field. Prepares the field work plan for CFSAN programs and acts as liaison with ORA to assure that CFSAN's program proposals are acceptable and reflect current policy.
- Monitors and maintains compliance programs and field assignments to assure up-to-date clear and useful guidance. Summarizes field accomplishments. Recommends program or assignment modifications to the CFSAN Offices.
- Provides accurate and timely data to Center management, other Offices, and ORA related field program accomplishment. Advises management of progress associated with the Center's budget, resource allocations and oversight responsibilities.
- Provides leadership and a focal point in the coordination and Center clearance of Compliance Policy Guides (CPGs).
- Supports ORA in the development of inspectional guidance and training of field personnel and provides technical assistance to field personnel.
- Provides expert support to the Office of Compliance or other Offices on policy development compliance case reviews and special projects at the request of the Office Director.
- Registers Low Acid Canned Foods (LACF) and Acidified Foods (AF) establishments and evaluates filed LACF processes.
- Serves as expert in acidified and low acid food technologies.
- Manages the Better Process Control School program and implementation of the LACF regulations through evaluation of thermal and non-thermal processing equipment and practices to determine the safety of food entered into commerce in the US.
- Supports the implementation of preventive control initiatives and programs in the preparation, packaging and holding of foods in cooperation with other CFSAN Offices.
- Plans and develops approaches to implement regulatory responsibilities in the Interstate Travel Program (ITP).
- Serves as the agency focal point for planning and coordinating, with other offices, initiatives and development of: program priorities that reflect a risk-based approach to mitigate food and environmental hazards, Work Plans, and Compliance Programs for the ITP.

- Provides information and technical assistance to agency and outside organizations on code interpretation and problem solving to maintain consistent interpretation of ITP handbooks, Codes and agency-developed standards for the interstate travel industry.

There are three teams and one branch within this division:

Data & Information Management Staff
Low Acid & Acidified Foods Team
Field Guidance Team
Compliance Program Branch

DIVISION OF COOPERATIVE PROGRAMS (HFS-625)

The functional statements for the Division of Cooperative Programs are:

- Develops and promotes adoption and implementation of guidance documents (including the Pasteurized Milk Ordinance, National Shellfish Sanitation Model Ordinance, the FDA Food Code, and related documents) for sound public health practices, food safety and security, compliance and enforcement, and regulatory programs related to retail food, Grade A milk and milk products, and molluscan shellfish.
- Serves as the principal agency liaison with the following National Conferences in administering the federal portion of the federal/state cooperative programs via Memoranda of Understanding between the Conferences and FDA: The National Conference on Interstate Milk Shipments (NCIMS); The Conference for Food Protection (CFP); and The Interstate Shellfish Sanitation Conference (ISSC).
- Develops policy, position papers, interpretations and regulatory guidelines related to the safety and security of Grade “A” milk and milk products, retail foods, and molluscan shellfish.
- Reviews and accepts or rejects the sanitary design and construction standards for milk and food equipment that are collectively developed by state health officials, dairy producer and processor groups, and dairy and food equipment manufacturers and suppliers.
- Provides information and technical assistance to agency and outside groups, individuals, and organizations on recommended guidance documents interpretation, procedures, compliance, problem solving, action plans, sanitary equipment design and sanctions to maintain uniform implementation of agency guidance documents for retail food, Grade A milk and milk products, and molluscan shellfish.
- Conducts a national certification program for state laboratories testing dairy products and other foods.
- Provides consultation to FDA, and outside organizations on laboratory equipment, apparatus, methods, and facilities problems associated with laboratory examination of foods.
- Standardizes, certifies, and evaluates/audits FDA staff and state and other jurisdictions’ staff; provides technical support to federal, state, and territorial staff and others relevant to standardizing and certifying state/local staff and about auditing cooperative programs; and evaluates/audits state and international milk and shellfish programs, including shellfish laboratories.

- Conducts and/or participates in the preparation and delivery of FDA and/or state seminars, conferences, workshops, and training courses regarding laboratory methodology and the safety and security of retail food, Grade A milk and milk products, and molluscan shellfish. Trains and certifies state and international Shellfish Laboratory Evaluation Officers.
- Evaluates state and international shellfish laboratories.
- Assists states, in assessing the affect of pollution sources on shellfish growing water quality through conducting hydrographic studies, shoreline surveys, data collection and interpretation for classification of Estuarine and river systems.
- In collaboration with other Center Offices and ORA, serves as the agency focal point to identify emerging needs, and to plan, develop, and coordinate, for the Center, field activities via compliance programs, field assignments, special investigations, and work plans, as they relate to retail food, Grade A milk and milk products, and molluscan shellfish.

There are four teams within this division:

Retail Food Protection Team
Milk Safety Team
Shellfish Program Implementation Team
Laboratory Quality Assurance Team

OFFICE OF COSMETICS AND COLORS (OCAC) (HFS-100)

DIVISION OF PROGRAMS AND ENFORCEMENT POLICY (HFS-105)

- Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions on issues related to cosmetic ingredients and products, color additive certification, color additive diluents, and products containing color additives.
- Reviews proposed regulatory actions referred by the Office of Compliance for program policy consideration and provides technical evaluation on cases related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office.
- Manages the review of petitions and evaluates and prepares the necessary action on petitions submitted to the Agency related to the functions of this Office.
- Administers the Agency's Color Certification and Cosmetic Registration Programs.

There are two branches within this division:

Cosmetics Programs and Regulations Branch
Color Certification Branch

OFFICE OF NUTRITIONAL PRODUCTS, LABELING, AND DIETARY SUPPLEMENTS (ONPLDS)

OFFICE OF THE DIRECTOR (HFS-800)

The functional statements for the Office of the Director are:

- Develops policy and regulations for dietary supplements, nutrition labeling and food standards.
- Develops the scientific evaluation to support those regulations and related policy developments.
- Supports enforcement actions and conducts clinical reviews and the summary of data of adverse events associated with dietary supplements and infant formula.

DIVISION OF DIETARY SUPPLEMENT PROGRAMS (HFS-810)

The functional statements for the Division of Dietary Supplement Programs are:

- Coordinates most agency activity relating to dietary supplements by responding to premarket notifications for new dietary ingredients and reviewing structure-function claims for dietary supplements.
- Promulgates and administers regulations relating to those activities as well as good manufacturing procedures for dietary supplements.
- Establishes a research agenda for collecting scientific information about the safety of dietary supplements.
- Coordinates actions to monitor and enforce industry compliance.

There are three teams within this division:

Review and Regulations Team

- Develops policies, position papers, and advisory opinions on issues related to dietary supplements. Provides regulatory guidance and assistance to Federal and State agencies and industry concerning regulatory requirements.
- Performs promulgation, amendment and regulatory maintenance of regulations related to dietary supplements, including Good Manufacturing Practices (GMPs).
- Manages the review of and response to notifications for new dietary ingredients for dietary supplements.
- Provides technical comment and support on issues relating to dietary supplement labeling, safety and nutrition.
- Prepares written responses to petitions and other correspondence.

Compliance and Enforcement Team

- Provides support and guidance to the field, in cooperation with the Office of Compliance, in handling regulatory actions and provides Headquarters assistance in the development, management, and cooperation of cases.
- Reviews proposed regulatory actions referred by the Office of Compliance, and provides technical evaluations on cases related to dietary supplements.
- Develops compliance policy, compliance strategies, regulatory guidance and enforcement policies related to dietary supplements compliance and enforcement.
- Responds to requests for Certificates of Export (Certificates of Free Sale) with respect to dietary supplements and to specific products that are the responsibility of this Office.
- Manages the review of and responds to notifications for structure/function claims. Evaluates the use of structure/function claims and recommends action.

Clinical Evaluation Team

- Monitors and evaluates adverse events and other sources of signals related to the safety of dietary supplement products.
- Provides clinical and scientific expertise in the risk assessment on dietary supplements to assist the Office Director and other key staff on dietary supplement policy issues and other related compliance issues; provides clinical responses to petitions, initiatives, and related dietary supplement activities.
- Provides clinical evaluation of the safety information provided in New Dietary Ingredient notifications.
- Coordinates and participates in advisory committee activities related to dietary supplements products.
- Participates in development of outreach programs and messages which provide information to consumers.
- Plans and coordinates research on clinical aspects of dietary supplements

FOOD LABELING AND STANDARDS STAFF (HFS-820)

This staff consists of the Regulations and Review Team and the Compliance and Enforcement Team.

Regulations and Review Team

- Develops regulations, compliance policies and guidance documents on non-nutritional aspects of food labeling (e.g., common or usual names, ingredient labeling, warning statements) and food standards of identity, quality and fill of container.
- Issues temporary marketing permits to firms for test marketing foods that deviate from current food standards.
- Manages the review of petitions and evaluates and prepares the necessary action on petitions submitted to the Agency on issues related to food labeling and food standards.
- Responds to requests for input in the development of Center and Agency positions for Congressional inquiries, official reports, pending legislation and formal responses to the Department related to food labeling and food standards.
- Responds to letters and other inquiries from consumers, industry, academia, Congress and other government agencies regarding regulatory issues related to food labeling and food standards.

- Provides regulatory guidance to FDA, other federal agencies, States, industry representatives and trade associations on issues involving food labeling and food standards of identity, standards of quality and fill of container.

Compliance and Enforcement Team

- Provides support and guidance to the field, in cooperation with the Office of Compliance (OC) for all domestic and import legal actions (e.g., warning letters, seizures, import detentions and reconditioning proposals) involving conventional foods, medical foods, infant formulas and all aspects of food labeling.
- Provides compliance and enforcement guidance to CFSAN's OC, Field Investigators and Compliance Officers, other FDA Offices, industry representatives, trade associations, and State and local government agencies.
- Provides regulatory assistance on conventional food and infant formula recalls.
- Provides compliance and enforcement guidance to the Infant Formula Clinical Team and participates in infant formula foreign inspections with FDA field investigators.
- Develops compliance policies, enforcement strategies and regulatory guidance for domestic and imported conventional foods, medical foods and infant formulas.
- Responds to consumer complaints, trade complaints, Congressional inquiries and industry requests on enforcement and compliance matters pertaining to conventional foods, medical foods, infant formulas and all aspects of food labeling.
- Initiates enforcement actions (e.g., warning letters) in response to trade complaints.
- Participates in international activities such as FDA's Trilateral Health Fraud Initiative and the U.S./Canada/Mexico Trilateral Technical Working Group on Food Labeling, Packaging and Standards.

Nutrition Programs and Labeling Staff (HFS-830)

- Responsible for scientific and regulatory review of nutrition labeling issues, such as health claims and nutrient content claims; food fortification; and changes to the Nutrition Facts Panel (e.g., *trans* fatty acid).
- Develops guidance documents, promulgates and administers regulations, and sets policy related to nutrition labeling.

This Staff is comprised of a Regulations and Review Team and a Nutrition Science Evaluation Team.

<u>Regulations and Review Team</u>

- Responds to health claim and nutrient content claim petitions and notifications within the requirements of the law and FDA regulations.
- Develops regulations, compliance policies and guidance documents on the nutritional aspects of food labeling (e.g., nutrition labeling).
- Manages the review of petitions and evaluates and prepares the necessary action on petitions submitted to the Agency on issues related to nutrition.
- Responds to requests for input in the development of Center and Agency positions for Congressional inquiries, official reports, pending legislation and formal responses to the Department related to nutrition.
- Responds to letters and other inquiries from consumers, industry, academia, Congress and other government agencies regarding regulatory issues related to nutrition.

- Provides regulatory guidance to FDA, other federal agencies, States, industry representatives and trade associations on nutrition issues.

Nutrition Science Evaluation Team

- Develops and updates the evidence-based ranking system for review of health claims.
- Reviews the scientific evidence for proposed health and nutrient content claims.
- Reviews the scientific evidence for revising the Nutrition Facts Label.
- Prepares scientific reviews for letters of enforcement discretion, rule making and guidance documents.
- Provides expertise in nutrition science to FDA staff on various projects and nutrition policy issues.
- Participates in advisory committee activities related to nutrition.

Division of Research and Applied Technology (HFS-840)

- Provides expert advice to CFSAN and agency components on matters within the scope of responsibility of the Division.
- Serves as the principle Agency liaison on methods for assuring dietary exposure to substances in food and for evaluating the validity of dietary exposure estimates.

The Division consists of a Database Management and Evaluation Team and a Methods Development and Application Team.

Database Management and Evaluation Team

- Plans, conducts and evaluates the Food Package and Label Survey (FLAPS) and retail surveys for the Voluntary Nutrition Labeling Program.
- Develops nutrient databases and regulations to support required nutrient values for use in the Voluntary Nutrition Labeling Program.
- Maintains, develops, manages and analyzes large-scale databases of food consumption, food composition, food ingredients, sales of processed packaged food products, and product label information for use by the Agency to support policy, regulatory, and food safety assessment decisions.
- Coordinates the review of databases submitted for use in nutrition labeling and foods.
- Monitors United States populations and special subgroups relative to use and safety of foods.
- Coordinates with and initiates liaison activities for outside laboratory and analytical research including units such as the University of Mississippi, AOAC, and related organizations.

Methods Development and Application Team

- Originates, plans and conducts laboratory research related to the scope of responsibilities of the Office.
- Develops appropriate methods for food and dietary supplement analyses and, in cooperation with the Field, maintains the Center's analytical capability for food labeling compliance.
- Initiates and supports review of food product labeling for accuracy of nutrient composition and content. Coordinates enforcement actions with other Office units.
- Serves as the Center's analytical resource for food labeling compliance and coordinates with, among others, FDA's Field laboratories, the Association of Official Analytical

Chemists, the American Oil Chemists Society, and the Univ. of Mississippi.

Infant Formula and Medical Foods Staff (HFS-850)

- Responds to data and notifications from manufacturers of all new or modified infant formulas, and provides counsel and review in the areas of nutritional science and medical science.

The Staff consists of a Regulations and Review Team and a Clinical Evaluation Team.

Regulations and Review Team

- Reviews formulation, nutrition, and processing information provided in notifications from manufacturers of new or modified infant formulas.
- Participates in development of new regulations for infant formulas and medical foods.
- Provides scientific support and participates in advisory committee activities related to infant formula products.
- Participates in development of outreach programs and messages which provide information to health care professionals and consumers.
- Provides scientific support for infant formula and medical foods deliberations for the Codex Committee on Nutrition and Foods for Special Dietary Use.
- Provides scientific expertise on issues related to infant formula and medical foods to assist the Office Director and other key staff on infant formula and medical foods policy issues and other related compliance issues.
- Provides scientific consultation to the Office of Compliance about compliance issues for infant formulas and medical foods.

Clinical Evaluation Team

- Monitors and evaluates adverse events and other sources of signals related to the safety of infant formula and medical foods products.
- Provides clinical and scientific expertise on issues related to infant formula and medical foods to assist the Office Director and other key staff on infant formula and medical foods policy issues and other related compliance issues.
- Provides clinical evaluation of the growth information provided in 90 day infant formula notifications.
- Provides scientific support and participates in advisory committee activities related to infant formula products.
- Participates in development of outreach programs and messages which provide information to health care professionals and consumers.
- Provides clinical consultation to the Office of Compliance about compliance issues for infant formulas and medical foods.

OFFICE OF PLANT AND DAIRY FOODS (OPDF) (HFS-300)

DIVISION OF PLANT PRODUCT SAFETY (HFS-305)

- Develops, collects, and interprets data regarding the safety, composition, quality, and manufacture of plant and plant products, bottled water, and miscellaneous products.
- Develops policy, regulations, position papers, regulatory guidelines, compliance

strategies, and advisory opinions on issues related to plant and plant product safety.
- Provides expert policy, scientific and technical advice, and assistance to the Center Director, other key officials, and the field on plant product safety issues, field programs, initiatives, and other related activities.
- Reviews proposed regulatory actions referred by the Office of Compliance for policy consideration and provides technical evaluation and necessary scientific support on cases related to plant and plant product issues.
- Reviews petitions on plant and plant product issues related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office regarding plant and plant products, bottled water, and other miscellaneous issues.

RISK ASSESSMENT STAFF (HFS-355)

- Develops the Center for Food Safety and Applied Nutrition's (CFSAN's) monitoring/surveillance programs for pesticide residues, industrial chemicals, toxic elements, and natural toxins in foods.
- Serves as CFSAN's resource for technical information on Agency monitoring programs and data regarding pesticide residues, industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Proposes, develops, and manages research initiatives for toxicological studies that will serve the needs of the Office's programs mandates.
- Provides toxicological evaluations related to the presence of industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Develops new risk assessment methodologies for risk assessments particularly in the area of dose-response assessment of industrial chemicals, process induced, toxic elements and natural toxins in foods.
- Provides safety and quantitative risk assessments on industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Provides toxicological evaluations and risk assessments on a consultative basis for other program offices.

DIVISION OF DAIRY AND EGG SAFETY (HFS-365)

- Develops, collects, and interprets data regarding the safety, composition and quality of eggs, manufacture of dairy products, and food products containing dairy or egg ingredients.
- Develops policy, regulations, position papers, regulatory guidelines, compliance strategies and policies, and advisory opinions on issues related to the safety of milk, eggs, and derived products.
- Provides expert policy, scientific, and technical advice and assistance to the Center Director, other key officials, and the field on dairy and egg safety issues, field programs, initiatives, and other related activities.
- Reviews proposed regulatory actions referred by the Office of Compliance for program policy considerations and provides technical evaluation and necessary scientific support on cases related to milk and egg issues.
- Reviews petitions on milk and egg issues related to this Office.

- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office regarding dairy, egg, game meat, and other miscellaneous issues.

OFFICE OF SEAFOOD (OS) (HFS-400)

DIVISION OF PROGRAMS AND ENFORCEMENT POLICY (HFS-415)

- Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions on issues related to seafood.
- Reviews proposed regulatory actions referred by the Office of Compliance for program policy consideration and provides technical evaluations on cases related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs, for the development of Agency seafood resource allocation recommendations, and the implementation of the laws and regulations related to this Office.
- Reviews petitions for implementing action levels set by this Office.

There are two branches within this division:

Policy and Guidance Branch
Programs and Enforcement Branch

1-7 CENTER FOR VETERINARY MEDICINE (CVM)

OFFICE OF SURVEILLANCE AND COMPLIANCE (HFV-200)

The functional statements for the Office of Surveillance and Compliance are:

- Advises the Center Director on surveillance and compliance policy concerning FDA regulatory responsibility with respect to animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.
- Develops and evaluates surveillance and monitoring programs to ensure the safety and effectiveness of animal drugs, and to detect emerging resistance to antimicrobials among zoonotic enteric pathogens.
- Plans, develops, monitors, and evaluates Center surveillance and compliance programs and coordinates their field implementation to ensure the safety and effectiveness of marketed animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.
- Directs and coordinates the development of scientific evidence supporting Formal Evidentiary Hearings requested by the Center.
- Recommends to the Center Director the amendment or withdrawal of approved new animal drugs applications.
- Develops, coordinates, and directs the Center's Voluntary Bioresearch Monitoring Program to ensure reliability of information on which to base new animal drug and food additive approvals.
- Provides epidemiology expertise to the Center as needed.

The three divisions in this Office are:

Division of Surveillance
Division of Animal Feeds
Division of Compliance

Note: The Division of Epidemiology (HFV-250) no longer exists. Its functions have been distributed throughout CVM. For information contact : 240-453-6830.

DIVISION OF SURVEILLANCE (HFV-210)

The functional statements for the Division of Surveillance are:

- Evaluates the safety and effectiveness of marketed animal drugs, special dietary feeds, veterinary medical devices, and other veterinary medical products and recommends action to correct deficiencies resulting from inadequate directions for use, warnings, and cautionary information.
- Evaluates drug product labels and other information to determine new animal drug status, regulatory priority, acceptable conditions of use, and need for regulatory activity. Maintains and makes available inventory listings of all marketed animal drugs to ensure adequate information is available for regulatory activity and customer support. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.
- Reviews marketed product labeling and makes recommendations concerning label revisions, regulatory supplements, suspension of manufacturing, and withdrawal of approval of new animal drugs to ensure marketed products are safe and effective.
- Monitors and evaluates promotion of marketed veterinary drugs to ensure promoted claims are consistent with approved claims.
- Conducts continuing surveillance and veterinary medical evaluations of clinical experience and required reports.
- Evaluates reports of product adverse experiences to ensure labeling contains a current accurate safety profile, identifies unsafe products, and unsafe product uses. Maintains liaison with other agencies and organizations engaged in similar activities to identify product interactions and coordinate activities. Participates in outreach programs to encourage veterinarians to participate in the pharmacovigilance program.
- Manages compliance programs covering regulated industries in animal drugs, veterinary medical devices, and other veterinary medical products to ensure the effectiveness of the programs. Reviews establishment inspection reports, labeling, and other findings to determine whether regulated products are being marketed in accordance with the Federal Food, Drug, and Cosmetic Act (the Act) and Agency regulations and policy.

There are three teams in this division:

Marketed Product Information
Scientific and Regulatory Review-Specified Products I
Scientific and Regulatory Review-Specified Products II

DIVISION OF ANIMAL FEEDS (HFV-220)

The functional statements for the Division of Animal Feeds are:

- Evaluates food additive petitions, and generally recognized as safe (GRAS) petitions and investigational food additive applications for adequacy of animal safety and utility data, active ingredient stability, labeling, and manufacturing facilities and controls; and coordinates the review of the human food safety and environmental impact information.

Recommends approval to the Center Director.

- Approves medicated feed mill licenses after being assured that the facility can manufacture and label medicated feed in compliance with Agency regulations.
- Evaluates the safety of complete animal feeds, dietary supplements, and feed ingredients and provides risk assessments on the toxic effects of contaminants of animal feed.
- Evaluates safety data, manufacturing and use information, and labeling for feeds and non-drug substances added to animal feeds to determine their legal status.
- Recommends and may participate in intramural and extramural research projects conducted or coordinated by the Office of Research to gain information on contaminants, drugs, and food additives.
- Provides technical and scientific assistance to and coordinates activities with state feed control offices and the Association of American Feed Control Officials (AAFCO) committees and task forces.
- Develops, monitors and evaluates CVM compliance programs or field assignments for medicated feeds, Type A medicated articles, and feed contaminants (mycotoxins, pesticides, heavy metals, industrial chemicals). Reports the findings from the programs to the states, FDA field, and other interested parties.

There are three teams within this division:

Animal Feed Safety Team
Medicated Feeds Team
Nutrition and Labeling Team

DIVISION OF COMPLIANCE (HFV-230)

The functional statements for the Division of Compliance are:

- Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal drugs, feeds, feed additives, veterinary medical devices, and other regulated products intended for animal use. Prepares and issues guidance to the field.
- Prepare, initiate, review, and/or concur with and approve regulatory actions involving such areas as unapproved new animal drugs, tissue residues, good manufacturing practice violations, label/labeling deficiencies, and violations for products intended for food animal as well as companion animal use. Coordinate appropriate investigative and regulatory follow up through consultation with other Center and Agency resources. Review submissions from the field and recommend whether submitted regulatory actions can be supported and should be further pursued by the Agency.
- Coordinates and prepares compliance and enforcement oriented replies in follow up to inquiries and complaints from consumers, industry, state and federal governments, Congress, etc.
- Manages, prepares and oversees revisions in the Center's compliance programs and in the on-going surveillance activities of the Center.
- Coordinates and manages CVM's on-going efforts to provide information, education and guidance for compliance efforts in areas such as Tissue Residues, Aquaculture, Bovine Spongiform Encephalopathy (BSE), Milk Residues, and zoonotic diseases.
- Reviews, prepares and issues Export Certificates for various veterinary products as

requested by foreign countries.
- Manages Center efforts and coordinates product recalls with Agency field offices.
- Prepares and issues assignments and manages/monitors surveillance and compliance activities under three of the Agency's Bioresearch Monitoring Programs: Sponsor-Monitor; Good Laboratory Practices; and Clinical Investigators.
- Manages administrative actions for the Center, including: withdrawal of new animal drug applications; revocation of feed mill licenses; disqualification of clinical investigators and other activities under the Application Integrity Policy.
- Evaluates regulatory approaches to human food safety concerns, including the monitoring of violative levels of harmful drugs in meat and poultry in response to reports of findings received from USDA/FSIS. Develops strategies designed to prevent food safety problems associated with pathogens and residues.
- Oversees the Center's efforts in providing education and training in CVM program areas and compliance related issues.

There are three teams within this division:

Enforcement and Regulatory Policy Team
BIMO and Administrative Actions Team
Compliance Information Management Team

1-8 ENFORCEMENT POLICY DIRECTORY

The most current version of this Directory is available on FDA's Intranet Website.

OFFICE OF REGULATORY AFFAIRS (ORA) HEADQUARTERS

Associate Commissioner for Regulatory Affairs (ACRA)
ACRA (HFC-1) 301-827-3101
Deputy ACRA (HFC-2) 301-827-3101
Assistant Commissioner for Regulatory Affairs (HFC-1) 301-827-4225

Office of Enforcement (OE)
Director, OE (HFC-200)..... 240-632-6800
Compliance Policy Council
Internet Regulatory Policy and Enforcement
Director of Compliance, OE (HFC-201)..... 240-632-6800
Director, Division of Compliance Management and Operations (HFC-210) 240-632-6850
Director, Division of Compliance Policy (HFC-230)..... 240-632-6860
Director, Division of Compliance Information and Quality Assurance (HFC-240).....240-632-6820

Division of Compliance Management and Operations (HFC-210) 240-632-6850
Case Review and Management
Civil Money Penalties (Compliance)
Inspection Warrants
Recalls
Team Biologics (Compliance)
Warning Letter Database

Division of Compliance Policy (HFC-230)..... 240-632-6860
Bioresearch Misconduct and Monitoring
Good Guidance Practices (GGPs)
Good Laboratory Practices (GLPs)/Non-Clinical
Information Disclosure (including FOI)
Policy (Biologics, Civil Money Penalties, Cosmetics, Drugs, Foods, Medical Devices, Veterinary Medicine, and Radiation Emitting Electronic Products)
Publications (Compliance Policy Guides Manual, Enforcement Notes, Enforcement Story, Information Disclosure Manual, Regulatory Procedures Manual), Testimony

Division of Compliance Information and Quality Assurance (HFC-240)...240-632-6820
Electronic Records and Signatures (21 CFR Part 11)); Electronic Regulatory Information Assurance
FACTS Firm Profiles (COMSTAT)
Gold Disk
Government-Wide Quality Assurance Program (GWQAP)

Quality Management Systems (QMS)
Turbo EIR

Office of Regional Operations (ORO)
Director, ORO (HFC-100)..... 301-443-6230
Deputy Director, ORO (HFC-101)..... 301-443-6230
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(As of October 18, 2002 Emergency Operations has been organized structurally as Office of Emergency Operations, Office of Crisis Management, Office of the Commissioner)

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Internet and Health Fraud Team (HFD-315) 301-827-8930
Compounding Team (HFD-317)..... 301-827-8930
New Drugs and Labeling Team (HFD-318)..... 301-827-8930
Imports and Exports Team (HFD-319) 301-827-8930
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Deputy Director (HFD-320) 301-827-8940
Recall Coordinator/Drug Shortage Manager (HFD-320) 301-827-9039
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Preapproval Compliance & International Certificates/Submissions Team (HFD-323) 301-827-9013
Foreign Inspection Team (HFD-325)..... 301-827-9021
Case Management and Guidance Branch (HFD-326)..... 301-827-8941
Case Management Team (HFD-327)..... 301-827-9023
Guidance and Policy Development Team (HFD-329) 301-827-9031
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Surveillance and Data Analysis Branch (HFD-332)..... 301-827-9058
Surveillance Programs Team (HFD-333) 301-827-8929
Data Analysis & Information Management Team (HFD-335) 301-827-9058

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Chief, Field Operations Branch (HFZ-306)..... 240-276-0131
Chief, Information Processing and Office Automation Branch (HFZ-307)..... 240-276-0132
Director, Division of Bioresearch Monitoring (HFZ-310).... 240-276-0244
Chief, Program Enforcement Branch (HFZ-311)..... 240-276-0245
Chief, Special Investigations Branch (HFZ-312) 240-276-0125
Director, Division of Enforcement A (HFZ-320)..... 240-276-0165
Deputy Director, Division of Enforcement A (HFZ-320)..... 240-276-0344
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Chief, General Surgical Devices Branch (HFZ-323)..... 240-276-0163
Chief, Dental, ENT and Ophthalmic Devices Branch (HFZ-331)..... 240-276-0352
Chief, OB/GYN, Gastroenterology and Urology Devices Branch (HFZ-332)..... 240-276-0356
Chief, General Hospital Devices Branch (HFZ-333)..... 240-276-0343
Director, Division of Enforcement B (HFZ-340)..... 240-276-0306
Deputy Director, Division of Enforcement B (HFZ-340)..... 240-276-0147
Case Expert (HFZ-340)..... 240-276-0294
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Chief, Cardiovascular and Neurological Devices Branch (HFZ-341)..... 240-276-0120
Chief, Orthopedic, Physical Medicine and Anesthesiology Devices Branch (HFZ-342) 240-276-0293
Director, Office of In Vitro Diagnostic Device Evaluation and Safety (HFZ-440)..... 240-276-0484
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Director, Office of Communication, Education and Radiation Programs (HFZ-200)…… 301-443-2845
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Chief, Electronic Products Devices Branch..... 240-276-0282
Chief, Diagnostic X-Ray Devices Branch 240-276-0120
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Domestic Branch (HFS-636)..... 301-436-2415
Import Branch (HFS-606) 301-436-2413
Director, Division of Field Programs (HFS-615) 301-436-2410
Compliance Program Branch (HFS-615) 301-436-1609
Low Acid & Acidified Foods Team (HFS-617)..... 301-436-2069
Field Guidance Team (HFS-607)..... 301-436-1611
Data & Information Staff (HFS-605)..... 301-436-2063
Director, Division of Cooperative Programs (HFS-625) 301-436-2439
Milk Safety Team (HFS-626) 301-436-2349
Retail Food Protection Team (HFS-627)..... 301-436-2350
Shellfish Program Implementation Team (HFS-628)….301-436-2439
Laboratory Quality Assurance Team (HFS-636)..... 301-436-2415

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Director, Division of Programs and Enforcement Policy (HFS-105) 301-436-1108
Cosmetics Programs and Regulations Branch (HFS-106)..... 301-436-1341
Color Certification Branch (HFS-107) 301-436-1136

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Deputy Director 301-436-2373
Division of Dietary Supplement Programs (HFS-810)
Director 301-436-2375
Regulations and Review Team 301-436-2375
Compliance and Enforcement Team 301-436-2375
Clinical Evaluation Team 301-436-2375
Food Labeling and Standards Staff (HFS-820)..... 301-436-2371
Director 301-436-2371
Regulations and Review Team 301-436-2371
Compliance and Enforcement Team 301-436-2371

Nutrition Programs and Labeling Staff (HFS-830)
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Regulations and Review Team..... 301-436-1450
Nutrition Science Evaluation Team 301-436-1450
Division of Research and Applied Technology (HFS-840)
Director 301-436-2377
Database Management and Evaluation Team 301-436-1788
Methods Development and Application Team 301-436-1777

Infant Formula and Medical Foods Staff (HFS-850)
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Regulations and Review Team 301-436-1450
Clinical Evaluation Team 301-436-1450

Director, Office of Plant and Dairy Foods and Beverages (HFS-300).... 301-436-1700
Director, Division of Plant Product Safety (HFS-305).... 301-436-1400
Regulatory Policy Branch (HFS-306) 301-436-2033
Implementation and Compliance Branch (HFS-307)..... 301-436-2032
Director, Division of Dairy and Egg Safety (HFS-365)... 301-436-2367
Regulatory Policy Branch (HFS-366) 301-436-1495
Implementation and Compliance Branch (HFS-367)..... 301-436-1494
Director, Risk Assessment Staff (HFS-355) 301-436-2402
Exposure Assessment Branch (HFS-357) 301-436-2042
Hazard Assessment Branch (HFS-356)..... 301-436-2402

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Director, Policy and Guidance Branch (HFS-416)..... 301-436-2303
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Team Leader, Team I-Specified Products (HFV-214)... 240-453-6844
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